

REMARKS/ARGUMENTS

In response to the Final Action Applicant has amended the application as follows:

5. Election/Restriction

Applicant has cancelled claim 24 without prejudice.

6. Claim Objections

Applicant has made the correction requested by the Examiner.

7. Claim Rejections 35 USC § 112

Applicant has corrected the claim dependency in claim 41 to depend from claim 36 rather than claim 35. Applicant respectfully submits that this renders the rejection moot.

8. Claim Rejections 35 USC § 103

The Examiner rejects the claims for being unpatentable over James et al. in view of Jaworski et al. The Examiner cites KSR (KSR, 82 USPQd2d at 1396) for the proposition that a specific teaching, suggestion or motivation is not required to support a finding of obviousness. The Examiner cites James et al. and Jaworski et al. for disclosing alternative FAE sequences from *Arabidopsis thaliana* and *Brassica napus* arguing that since these alternatives are highly homologous to the sequences recited in the present claims,

"it would have been obvious an within the scope of an ordinary skill in the art at the time the invention was made to isolate and identify claimed nucleotide sequences (variants of Jaworski et al. SEQ ID NO: 34) based on the polynucleotide sequence encoding Jaworksi et al. SEQ ID NO: 34 by applying

conventional methodologies of variant DNA isolation which had a reasonable expectation of success."

Applicant respectfully disagrees.

Firstly, the KSR case is directed to a factually different set of circumstances related to electronic pedal-position sensors in which all of the claimed elements were to be found in the prior art documents that were cited. This is not true in the present case. In the present case, neither James et al. nor Jaworski et al. nor a combination of the two disclose the sequences of the present claims. Even if it were obvious to try to find the *Crambe* FAE protein and gene, and even if the techniques for finding the *Crambe* FAE protein and gene were generally known in the art as alleged by the Examiner, this still does not amount to a finding of obviousness under 35 USC § 103.

Applicant would like to draw the Examiner's attention to the April 3, 2009 decision of the United States Court of Appeals for the Federal Circuit *In re Kubin*, CAFC 2008-1184 deciding on USSN 09/667,859 (Fed. Cir. 2009) in which the application of KSR to "classic biotechnology inventions" was discussed. The Court cites *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988) favorably as follows:

To differentiate between proper and improper applications of "obvious to try," this court outlined two classes of situations where "obvious to try" is erroneously equated with obviousness under § 103. In the first class of cases,

what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.

Id. In such circumstances, where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness. The inverse of this proposition is

succinctly encapsulated by the Supreme Court's statement in KSR that where a skilled artisan merely pursues "known options" from a "finite number of identified, predictable solutions," obviousness under § 103 arises. 550 U.S. at 421.

The second class of O'Farrell's impermissible "obvious to try" situations occurs where

what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

853 F.2d at 903. Again, KSR affirmed the logical inverse of this statement by stating that § 103 bars patentability unless "the improvement is more than the predictable use of prior art elements according to their established functions." 550 U.S. at 417.

Applicant submits that the Examiner's rejection of the present claims is an improper application of "obvious to try" under both classes of situations where "obvious to try" is erroneously equated with obviousness under § 103.

First, Applicant draws the Examiner's attention to the appended Declaration of Dr. David Taylor (and citations referenced therein) which compares the performance of the FAE genes from different species of plants by determining the relative increase in erucic acid 22:1 production. It is clear from the Declaration that the *Crambe* FAE gene which is the subject of the present invention provides unexpectedly superior results to the FAE genes from other species of plants including the FAE genes from *Arabidopsis thaliana* and *Brassica napus* which are the subject of the cited James et al. and Jaworski et al. references. It should be noted that SEQ ID NO: 34 of Jaworski et al. is a *B. napus* FAE variant that differs from the wild type *B. napus* FAE (SEQ ID NO: 4 of Jaworski et al.) by only 1 amino acid out of 506, making it much more homologous to the wild type *B. napus* FAE than to the *Crambe* FAE.

Thus, ectopic expression of *Crambe* FAE gene provides a 1.5 fold relative increase in erucic acid 22:1, while ectopic or over-expression of the other FAE genes only provides relative increases in the range of 1.1-1.25 fold. It should be noted that measurement of the relative increase is a better (and the only rational) method of comparison by removing species effects and focusing on the gene effect only. Such an improvement in erucic acid 22:1 production is very significant in the field of seed oil production, and, as stated in the Declaration:

"one would never have predicted that the *Crambe* FAE would perform better than others."

This clearly establishes that the claimed invention is an improvement that "is more than the predictable use of prior art elements according to their established functions", thereby being unobvious under the second class of O'Farrell's impermissible "obvious to try" situations. Further, as discussed in MPEP 716.02(a), "Evidence that a compound is unexpectedly superior in one of a spectrum of common properties . . . can be enough to rebut a prima facie case of obviousness".

Second, as evidenced by the appended BLAST P alignment comparison between SEQ ID NO: 24 of the present invention and SEQ ID NO: 34 of Jaworski et al., the two sequences have 92% sequence identity rather than 97% as alleged by the Examiner. Further, SEQ ID NO: 34 of Jaworski et al. differs from the wild type *B. napus* FAE (SEQ ID NO: 4 of Jaworski et al.) by only 1 amino acid out of 506. The number of possible variations of Jaworski et al.'s SEQ ID NO: 34 are, for practical purposes, so large as to be infinite and unpredictable, even at such a high homology level, that a skilled person cannot merely pursue known options on a finite number of identified, predictable outcomes to arrive at the currently claimed sequences. A skilled person would be merely "throwing metaphorical darts at a board filled with combinatorial prior art possibilities". Thus, Applicant submits that the presently claimed invention is also unobvious under the first class of O'Farrell's situations where "obvious to try" is erroneously equated with obviousness under § 103.

Even if the obviousness rejection is improper under only one of O'Farrell's classes of situations, a finding of unobviousness is required. In this case, the obviousness rejection is improper under both of O'Farrell's classes of situations. The Examiner is respectfully requested to reconsider and withdraw the 35 USC § 103 rejections.

Early and favorable consideration of the application is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees, and credit any over payments, to Deposit Account No. 501593, in the name of Borden Ladner Gervais LLP.

Respectfully submitted,

DLC/bmp

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Encls.

1. Declaration of David Taylor dated May 20th, 2010
2. Crambe-Jaworski Blast P alignment 11530-1.txt